

## Protection of Human Subjects in Research (Attachment to Title Page Form)

### I. Instructions to Applicants about the Narrative Information that Must be Provided if Research Activities Involving Human Subjects are Planned.

If you marked item 8 on the application “Yes” and designated exemptions in 8a, **(all research activities are exempt)**, provide sufficient information in the application to allow a determination that the designated exemptions are appropriate. Research involving human subjects that is exempt from the regulations is discussed under **II.B. “Exemptions,”** below. The Narrative must be succinct. **Provide this information in an “Item 8/Protection of Human Subjects Attachment” and insert this attachment immediately following the Title Page Form.**

If you marked “Yes” to item 8 on the face page, and designated no exemptions from the regulations **(some or all of the research activities are nonexempt)**, address the following six points for each nonexempt activity. In addition, if research involving human subjects will take place at collaborating site(s) or other performance site(s), provide this information before discussing the six points. Although no specific page limitation applies to this section of the application, be succinct. Provide the six-point narrative and discussion of other performance sites in an **“Item 8/Protection of Human Subjects Attachment” and insert this attachment immediately following the Title Page Form.**

(1) Provide a detailed description of the proposed involvement of human subjects. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, children with disabilities, adults with disabilities, persons with mental disabilities, pregnant women, prisoners, institutionalized individuals, or others who are likely to be vulnerable.

(2) Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

(3) Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

(4) Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

(5) Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of the subjects.

(6) Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

### II. Information on Research Activities Involving Human Subjects

#### A. Definitions.

A research activity involves human subjects if the activity is research, as defined in the Department’s regulations, and the research activity will involve use of human subjects, as defined in the regulations.

#### —Is it a research activity?

The ED Regulations for the Protection of Human Subjects, Title 34, Code of Federal Regulations, Part 97, define research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” *If an activity follows a deliberate plan whose purpose is to develop or contribute to generalizable knowledge, such as an exploratory study or the collection of data to test a hypothesis, it is research.* Activities which meet this definition constitute research whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

#### —Is it a human subject?

The regulations define human subject as “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” (1) *If an activity involves obtaining information about a living person by manipulating that person or that person’s environment, as might occur when a new instructional technique is tested, or by communicating or interacting with the individual, as occurs with surveys and interviews, the definition of human subject is met.* (2) *If an activity involves obtaining private information about a living person in such a way that the information can be linked to that individual (the identity of the subject is or may be readily determined by the investigator or associated with the information), the definition of human subject is met.* [Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an

individual and which the individual can reasonably expect will not be made public (for example, a school health record).]

## **B. Exemptions.**

Research activities in which the only involvement of human subjects will be in one or more of the following six categories of **exemptions** are not covered by the regulations:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. ***If the subjects are children, this exemption applies only to research involving educational tests or observations of public behavior when the investigator(s) do not participate in the activities being observed.*** [Children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law or jurisdiction in which the research will be conducted.]

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under section (2) above, if the human subjects are elected or appointed public officials or candidates for public office; or

federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S Department of Agriculture.

***Copies of the Department of Education's Regulations for the Protection of Human Subjects, 34 CFR Part 97 and other pertinent materials on the protection of human subjects in research are available from the Grants Policy and Oversight Staff (GPOS) Office of the Chief Financial and Chief Information Officer, U.S. Department of Education, Washington, D.C., telephone: (202) 708-8263, and on the U.S. Department of Education's Protection of Human Subjects in Research Web Site at <http://ocfo.ed.gov/humansub.htm>.***